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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/008,224	11/06/2001	Isaac B. Horton III	1300-015	6966

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EXAMINER	
CHORBAJI, MONZER R	
ART UNIT	**PAPER NUMBER**
1744	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/008,224	HORTON, ISAAC B.	
	Examiner	Art Unit	
	MONZER R. CHORBAJI	1744	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *23 July 2007*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-17,19-39 and 41-61* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-17,19-39 and 41-61* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *06 November 2001* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

This non-final action is in response to the RCE/Amendment received on 07/23/2007

Claim Rejections - 35 USC § 102

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

2. The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) and the Intellectual Property and High Technology Technical Amendments Act of 2002 do not apply when the reference is a U.S. patent resulting directly or indirectly from an international application filed before November 29, 2000. Therefore, the prior art date of the reference is determined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

3. Claims 1-4, 9-17, 19-27, 30, 33, 35-39, 41-49, 52, 55 and 57-60 rejected under 35 U.S.C. 102(e) as being anticipated by Goodrich, Jr. et al (U.S.P.N. 6,258,577) and if necessary as evidenced by "Electromagnetic Spectrum" Internet printout.

Regarding claims 1 and 39, Goodrich discloses a blood purification system (figure 7) and a method for sterilizing microorganisms in blood (col.3, lines 50-55 and col.4, lines 1-4 where killing microorganisms is equivalent to sterilization of microorganisms) including the following: a blood purifier (rectangular structure labeled 194 in figure 7) that produces a UV dose (UV dose is produced within the blood purifier

at the unlabeled connection between 164 and 162) with a housing (figure 7:164) that include an inlet and outlet (unlabeled inlet and outlet in figure 7), the housing being UV reflective (in col.12, lines 47-50 and col.13, lines 4-6, Goodrich teaches placing a reflective surface in touching orientation with the walls of the decontamination cuvette 164 in figure 7. Placing the reflective surface in a touching orientation with the wall of the decontamination cuvette is considered to be an integral part of walls of the housing structure 164 shown in figure 7 such that the housing is UV reflective), providing a UV light source (figure 7:160) connected by an optical connection (figure 7:162) positioned to provide a focused, controllable light output (col.7, lines 66-67, col.8, lines 1-5, col.10, lines 24-30 and col.13, lines 15-18) to the blood purifier (rectangular structure labeled 194 in figure 7), a control mechanism (col.8, lines 8-14), a UV dose zone (unlabeled total inner volume within housing 164) in the housing, the dose zone includes a dose region for the effective sterilization of microorganisms in a blood (unlabeled right inner volume part within housing 164 in figure 7), activating the UV light source (example 6) and passing the blood through the housing (figure 7:186, 164 and 188) in order to provide a sterilized blood. In addition, the light source in the system of Goodrich is capable of providing light output between about 250 nm and about 260 nm. Goodrich teaches that wavelengths in the ultraviolet to visible range can be used as well (col.7, lines 20-28). See the "Electromagnetic Spectrum" Internet printout where the ultraviolet range is known to be between 10-400 nm.

Regarding claims 2-4, 10-14, 17, 26-27, 30, 48 and 52, Goodrich teaches the following: the light source includes a UV lamp (figure 7:160), optic (figure 7:162), a

housing (figure 7:164), a power supply (a necessary inherent feature in order for the apparatus to function), light source that includes an optical component positioned to provide a focused (col.13, lines 15-18), controllable light output (col.8, lines 1-4), light source is UV transmissive (inherent property of fiber optics to totally transmit light through internal reflection), light source is UV reflective (inherent property of fiber optics whose internal core is made up of material with high refractive index), light source optical component are reflectors (inherent property of fiber optics whose internal core is made up of material with high refractive index), a fiber optic transmission line (inherent property of fiber optics to totally transmit light through internal reflection), blood purifier (rectangular structure labeled 194 in figure 7) includes a dose zone (unlabeled inner volume within housing 164) and a housing, dose zone includes a delivery device (inactivated blood at the end of the volume within the housing 164 is delivered to line 188), end-emitting fiber optic transmission lines (figure 7:unlabeled end of 162 connected to 164) and the delivery device with a planar configuration (the decontaminated blood product line has an inherent two-dimensions, which are diameter and length).

Regarding claims 9, 15-16, 19-25, 33, 35-38, 41-47, 49, 55 and 57-60, Goodrich teaches the following: the UV lamp (figure 7:160) is capable of emitting light in the UVV and UVC wavelengths, the fiber optic line (figure 7:162) is capable of being removably connectable to the light source (figure 7:160) and the blood purifier (figure 7:194), the use of glass lines optical fibers (col.13, lines 15-16), the dose zone includes a portal (unlabeled opening in housing 164 for the entrance of light guide 162 in figure 7) for

removable connection to a fiber optic transmission line, the portal optical component (unlabeled part of light guide 162 within housing 164 in figure 7) positioned between the portal opening and the interior of the blood purifier, portal optical component is UV transmissive (light guide 162 in figure 7 transmits light within it), portal optical component is UV reflective (light guide 162 in figure 7 reflects light within its interior walls), portal optical component includes reflectors (col.8, lines 1-3), blood purifier uses enhanced two-dimensional design (blood purifier 194 in figure 7 has a depth and length parameters) to improve the blood purification, blood purifier uses enhanced three-dimensional design (blood purifier 194 in figure 7 has depth, width and length parameters) to improve the blood purification, interior surface of the blood purifier is a UV reflective surface (figure 7:194 and 163), the interior of the blood purifier includes interior optical component (unlabeled part of light guide 162 extending within blood purifier 194 in figure 7 and is attached to housing 164) that is attached to the interior surfaces, interior optical component is UV transmissive (unlabeled part of light guide 162 within housing 164 in figure 7 transmits light within it, interior optical component is UV reflective, interior optical component includes reflectors (unlabeled part of light guide 162 within housing 164 in figure 7 reflects light within its interior walls), housing (unlabeled port in housing 164 in figure 7 where light guide 162 is connected to the housing) includes a portal for removable connection to a fiber optic line (figure 7:162), portal optical component (unlabeled part of light guide 162 in figure 7 that is connected to housing 164) is capable of being positioned between the portal and the interior of the

blood purifier (figure 7:194) and the delivery device (entire decontamination assembly illustrated in figure 7) includes end-emitting fiber optic line.

Claim Rejections - 35 USC § 103

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

5. The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

6. Claims 34 and 56 are rejected under 35 U.S.C. 103(a) as being unpatentable over Goodrich, Jr. et al (U.S.P.N. 6,258,577).

Regarding claims 34 and 56, Goodrich discloses a blood purification system (figure 7) that includes a blood purifier (rectangular structure labeled 194 in figure 7) with a housing (figure 7:164) where the housing being UV reflective (in col.12, lines 47-50 and col.13, lines 4-6, Goodrich teaches placing a reflective surface in touching orientation with the walls of the decontamination cuvette 164 in figure 7. Placing the reflective surface in a touching orientation with the wall of the decontamination cuvette is considered to be an integral part of walls of the housing structure 164 shown in figure

7 such that the housing is UV reflective). Goodrich is silent with regard to the type of reflecting material. However, one of ordinary skill in the art would recognize that, for example, aluminum is known for its light rays reflecting properties and choosing the type of reflecting material is an obvious design choice that is within the scope of the artisan.

7. Claims 6-7 are rejected under 35 U.S.C. 103(a) as being unpatentable over Goodrich, Jr. et al (U.S.P.N. 6,258,577) as applied to claim 4 and further in view of Herter (U.S.P.N. 6,504,319).

Regarding claims 6-7, Goodrich teaches using UV lamps without specifically describing their types. Herter, which is in the art of designing UV emitting sources, describes that the use of electrode-less high-frequency discharge spectral lamps is known in the prior art (col.1, lines 34-36) and further teaches using electrode-less low pressure discharge lamps (col.1, lines 3-9) because they have low transmission losses and are suitable for board construction in a miniature size (col.2, lines 26-28). Thus, it would have been obvious to one of ordinary skill in the art at the time the invention was made to provide the system in Goodrich with the electrodeless lamp because they have low transmission losses and are suitable for board construction in a miniature size as shown by Herter (col.2, lines 26-28).

8. Claim 61 is rejected under 35 U.S.C. 103(a) as being unpatentable over Goodrich, Jr. et al (U.S.P.N. 6,258,577) and if necessary as evidenced by "Electromagnetic Spectrum" Internet printout and further in view of Gunn et al (U.S.P.N. 6,586,172).

Regarding claim 61, Goodrich discloses a method for sterilizing microorganisms in blood (col.3, lines 50-55 and col.4, lines 1-4 where killing microorganisms is equivalent to sterilization of microorganisms) including the following: providing a UV light source (figure 7:160) connected by an optical connection (figure 7:162) positioned to provide a focused, controllable light output (col.7, lines 66-67, col.8, lines 1-5, col.10, lines 24-30 and col.13, lines 15-18) to the blood purifier (rectangular structure labeled 194 in figure 7), a control mechanism (col.8, lines 8-14), a UV dose zone is produced (unlabeled total inner volume within housing 164) in the housing, the UV dose zone includes a dose region for the effective sterilization of microorganisms in a blood (unlabeled right inner volume part within housing 164 in figure 7), activating the UV light source (example 6), passing the blood through the housing (figure 7:186, 164 and 188) in order to provide a sterilized blood and providing a delivery device (figure 7:188 and 182). Goodrich teaches that wavelengths in the ultraviolet to visible range are used as well (col.7, lines 20-28). See the "Electromagnetic Spectrum" Internet printout where the ultraviolet range is known to be between 10-400 nm. Goodrich does not specifically teach that his blood purifier includes a vertical riser configuration. Gunn inactivates microorganisms in blood by UV irradiation (col.1, lines 13-21) where he passes the blood through a vertical riser configuration (figure 8:31, col.17, lines 63-67 and col.18, lines 1-3) where the blood is moved at a predetermined rate (figure 8:48) toward the UV light output (figure 8:35 and figure 9:36-37) where the blood is subjected to an increased UV dose as it approaches the light output in order to maximize inactivation and limit damage of blood (col.3, lines 26-31). Therefore, it would have been obvious to

one of ordinary skill in the art at the time the invention was made to provide the method in Goodrich with the vertical riser configuration in order to maximize inactivation and limit damage of blood as shown by Gunn (col.3, lines 26-31).

9. Claims 5, 8, 28-29, 31-32, 50-51 and 53-54 are rejected under 35 U.S.C. 103(a) as being unpatentable over Goodrich, Jr. et al (U.S.P.N. 6,258,577) as applied to claims 4, 26, 48 and further in view of Gunn et al (U.S.P.N. 6,586,172).

Regarding claims 5 and 8, Goodrich teaches using UV lamps without specifically describing their types. Gunn inactivates microorganisms in blood by UV irradiation (col.1, lines 13-21) and teaches irradiating with high-pressure mercury vapor lamps (col.14, lines 27-28) in order to provide radiation with longer wavelength UV light (col.14, lines 32-33). Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to provide the system in Goodrich with the high-pressure mercury vapor lamps in order to provide radiation with longer wavelength UV light as taught by Gunn (col.14, lines 32-33).

Regarding claims 31 and 53, Goodrich is silent as to describing the structural material of his blood purifier (figure 7:194). Gunn inactivates microorganisms in blood by UV irradiation (col.1, lines 13-21) and teaches that plastics (col.11, lines 60-61) is one of the preferred material for building the vessel of his UV irradiation device (figure 8:31) because plastics are biologically compatible/acceptable materials (col.11, lines 60-61). Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to provide the system in Goodrich with plastics because they are biologically compatible/acceptable materials as shown by Gunn (col.11, lines 60-61).

Regarding claims 28-29 and 50-51Goodrich does not specifically teach that his blood purifier includes vertical riser configuration. Gunn inactivates microorganisms in blood by UV irradiation (col.1, lines 13-21) where he passes the blood through a vertical riser configuration (figure 8:31, col.17, lines 63-67 and col.18, lines 1-3) where the blood is moved at a predetermined rate (figure 8:48) toward the UV light output (figure 8:35 and figure 9:36-37) where the blood is subjected to an increased UV dose as it approaches the light output in order to maximize inactivation and limit damage of blood (col.3, lines 26-31). In addition, Gunn's vertical riser configuration is capable of being dimensioned to various different sizes depending on the application it is utilized for. Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to provide the system in Goodrich with the vertical riser configuration in order to maximize inactivation and limit damage of blood as shown by Gunn (col.3, lines 26-31).

Regarding claims 32 and 54, Goodrich's blood purifier (figure 7:194) is capable of being disposable.

Response to Arguments

10. Applicant's arguments with respect to claims 1-17, 19-39 and 41-61 have been considered but are moot in view of the new ground(s) of rejection.

On page 13 of the Remarks section, Applicant argues that Goodrich uses photosensitizers in combination with UV light to decontaminate blood whereas the instant claims only uses UV light.

The instant claims do not exclude the use of photosensitizers such that both the instant claims and Goodrich inactivate pathogens in blood samples using UV light.

Remarks

11. The Terminal Disclaimer submitted on 07/23/2007 has been accepted.

Conclusion

12. Any inquiry concerning this communication or earlier communications from the examiner should be directed to MONZER R. CHORBAJI whose telephone number is (571) 272-1271. The examiner can normally be reached on M-F 9:00-5:30.

13. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, GLADYS J. CORCORAN can be reached on (571) 272-1214. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

14. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

MRC

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